

## **Remarks/Arguments**

### **DRAWINGS**

New formal drawings are submitted herewith. The formal drawing sheets include all of the figures appearing on the immediate prior version of the drawing sheets.

### **SPECIFICATION**

Applicants have amended the specification herein to correct typographical errors. No new matter was introduced by the amendments of the specification herein.

### **CLAIMS**

Claims 1-11 are currently pending in the application. Claims 10 and 11 have been newly added. In the Non-Final Office Action of September 14, 2005, the Examiner rejected pending claims 1-5 and 7-9 on various grounds. The Examiner objected to claim 6 for being dependent upon a rejected claim, but would be allowable if rewritten in independent form to include all of the limitations of claims 1-5. New claim 10 represents the invention of claim 6 and all intervening claims. The rejections to claims 1-5 and 7-9 are traversed. Applicants respond to each rejection as subsequently recited herein, and respectfully request reconsideration and further examination of the present application under 37 CFR § 1.112.

**A. Applicants traverse the Examiner's rejection of pending claims 1 and 7-8 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. US 6,730,116 to *Wolinsky et al.***

Applicants have thoroughly considered the Examiner's remarks concerning the patentability of claims 1 and 7-8 and have meticulously read *Wolinsky et al.* (hereinafter referred to as "*Wolinsky*"). In order for *Wolinsky* to qualify as a valid §102(b) reference with respect to the pending application, *Wolinsky* would have had to been "patented... *more than one year prior to the date of application for patent in the United States.*" See MPEP §2131. The Examiner's §102(b) rejection based on *Wolinsky* is improper on its

face because the issue date of *Wolinsky* (May 4, 2004) falls *after* the filing date of the pending patent application (filed on March 18, 2004, with claim of priority to provisional application filed on March 19, 2003). Accordingly, *Wolinsky* was not patented more than one year before the priority date (or the filing date) of the pending patent application.

Moreover, for this 35 U.S.C. §102(b) rejection or any other anticipation rejection to be proper, each and every element of the claims must be disclosed in as great detail by the reference as claimed in the claims. *See* MPEP §2131. Applicants respectfully traverse this anticipation rejection of claims 1 and 7-8 because *Wolinsky* does not teach or suggest the use of struts. The structural mechanism *Wolinsky* adopted for supporting a stent is quite different from that adopted by Applicants. For supporting stent structure, Applicants employ circumferential expanding elements that are essentially formed of struts and generally linear interconnecting elements. The struts and generally linear interconnecting elements are then connected by hinge elements. Accordingly, with the Applicants' stent, the inflection points are positioned at strain relief sections 18, 20 (connecting struts to interconnecting elements) and at hinge elements 22 (where two struts are pivotably connected), which form peaks 12p and troughs 12t.

By contrast, *Wolinsky's* stent does not employ actual struts for structural support of its circumferential expanding elements. Rather, *Wolinsky's* stent uses a "chain" of rings 91 joined together for structural support. The rings 91 are connected to each other at inflection points 92a and 92b. This mechanism is quite distinctive from the Applicant's, where inflection points are positioned at strain relief sections 18, 20 and at peaks and valleys, *but not* at the midpoint of the strut.

What the Examiner implies as a strut, as taught by *Wolinsky*, is upon closer review, actually two halves of two separate rings joined together at an inflection point. While the Examiner may argue that the regions formed near the inflection points are generally linear and loosely correspond to Applicant's struts, but then the Examiner would also have to acknowledge that these regions are formed of several distinct elements, namely two halves of two separate rings and an inflection point. Unlike the *Wolinsky* mechanism described above, Applicants use a single unit; that is a strut. The difference between *Wolinsky's* stent and the Applicant's stent is quite clear.

To conclude, while *Wolinsky* may have disclosed something (a region formed of two halves of two separate rings and an inflection point) that superficially corresponds to a strut, upon close inspection, *Wolinsky's* disclosure is *structurally quite different* from the strut disclosed by Applicants. Having not taught the use of an actual strut for structurally supporting a stent, *Wolinsky* therefore does not anticipate pending claim 1.

In addition to the arguments above, Applicants also respectfully traverse this anticipation rejection of claims 1 and 7-8 because *Wolinsky* fails to disclose, teach or suggest "struts, wherein the struts form generally linear sections and are interconnected at the peaks and valleys by hinge elements." Contrary to the Examiner's assertion, *Wolinsky* does not teach of incorporating struts to a stent. Instead, *Wolinsky* teaches of a stent formed of circumferential rings (91) connected by relatively straight links (90) at inflection points (92a-b). See *Wolinsky* Fig. 11 and col. 9 lns. 11-21. In pending claim 1, Applicants disclose struts and hinge elements not disclosed by *Wolinsky*. By employing struts and hinge elements, Applicants' stent lends a greater degree of compressibility to Applicant's stent than that found in *Wolinsky*, where struts and U-shaped hinge elements were not employed. Additionally, the rings (91) disclosed in *Wolinsky* are not generally linear in contrast to the generally linear struts disclosed by the Applicant. In fact, the rings in *Wolinsky* are shaped like sinusoidal curves. By definition, rings are curved surfaces and are therefore not generally linear. Therefore, *Wolinsky's* rings are geometrically dissimilar to the Applicant's disclosed generally linear struts. As such, it is abundantly clear to those having ordinary skill in the art that the rings (91) disclosed by *Wolinsky* in Fig. 9 are shaped like sinusoidal curves, and not shaped in a generally linear manner as disclosed by Applicants.

Accordingly, *Wolinsky* fails to disclose, teach or suggest "struts, wherein the struts form generally linear sections and are interconnected at the peaks and valleys by hinge elements" as required by independent claim 1. Withdrawal of rejection of independent claim 1 under §102(b) is respectfully requested.

Claims 7-8 depend from independent claim 1. Therefore, dependent claims 7-8 include all of the elements and limitations of independent claim 1. It is therefore respectfully submitted by Applicants that dependent claims 7-8 are allowable over

*Wolinsky* for at least the same reason as set forth herein with respect to independent claim 1 being allowable over *Wolinsky*. Therefore, withdrawal of the rejection of dependent claims 7-8 under §102(b) as being anticipated by *Wolinsky* is respectfully requested.

B. Applicants traverse the Examiner rejection of pending claims 1 and 9 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0123798 to *Burgermeister*.

Applicants have thoroughly considered the Examiner's remarks concerning the patentability of claims 1 and 9 in light of *Burgermeister*. Applicants respectfully traverse this §102(b) rejection of claims 1 and 9 because contrary to the Examiner's assertion, *Burgermeister* fails to disclose, teach or suggest "generally linear interconnecting elements interconnecting adjacent pairs of circumferential expansion elements" as disclosed in claim 1. (Emphasis added.) As clearly shown in Fig. 10, the interconnecting elements of *Burgermeister*'s stent bend in several directions, and therefore are *not* generally linear as commonly understood by those of ordinary skill in the art.

Additionally, *Burgermeister* fails to disclose generally linear struts as disclosed in currently amended claim 1. A close reading reveals that *Burgermeister* Fig. 10 (which was cited by the Examiner) shows generally curvy struts, not generally linear struts as described in pending claim 1. According to the Detailed Description of the Drawings, *Burgermeister* Fig. 10 is merely a "schematic[s] of the theory behind expansion of the stent of Fig. 8." Upon a review of Fig. 8, it is quite clear that the struts shown are generally curvy. As *Burgermeister* discloses in Paragraph 0052, "the radial struts 410 are formed from a generally 'wavy' pattern. This wavy pattern is useful in helping to reduce the crimp profile of the stent 400 on the balloon."

To conclude, *Burgermeister* fails to teach both generally linear interconnecting elements and generally linear struts. For this reason, the Examiner's anticipation rejection by *Burgermeister* is improper. Thus, withdrawal of rejection of independent claim 1 under §102(b) is respectfully requested.

With regard to claim 9, the Examiner's §102(b) rejection for being anticipated by *Burgermeister* is improper because *Burgermeister* does not teach of a stent elongating

along the longitudinal axis of the stent as it expands from a smaller diameter to a larger diameter. To be more precise, *Burgermeister* teaches only of reducing/preventing foreshortening of a stent as it expands (Paragraph 0035, Paragraph 0042, Paragraph 0043, Paragraph 0046) and maintaining the overall length of a stent (Paragraph 0051). To achieve this reduction/prevention of stent foreshortening, *Burgermeister* employs certain parts of a stent, such as canted members (Paragraph 0042), which lengthen longitudinally upon circumferential expansion. Nonetheless, this kind of longitudinal lengthening only involves lengthening of parts of a stent, so that overall stent length is maintained and stent foreshortening is reduced/prevented; the longitudinal lengthening disclosed by *Burgermeister* does *not*, however, involve longitudinal lengthening of *overall stent length* as disclosed by Applicants. If the Examiner disagrees with Applicants' reading of *Burgermeister*, Applicants kindly request the Examiner to cite in detail and with specificity where *Burgermeister* teaches of a stent elongating along the longitudinal axis of the stent as it expands from a smaller diameter to a larger diameter.

Applicants also note that claim 9 depends from independent claim 1. Therefore, dependent claim 9 includes all of the elements and limitations of independent claim 1. It is therefore respectfully submitted by Applicants that dependent claim 9 is allowable over *Burgermeister* for at least the same reason as set forth herein with respect to independent claim 1 being allowable over *Burgermeister*. Thus, withdrawal of the rejection of dependent claim 1 under §102(b) as being anticipated by *Burgermeister* is respectfully requested.

C. Applicants traverse the Examiner rejected pending claims 2-5 under 35 U.S.C. §103(a) as being unpatentable over *Wolinsky et al.* in view of *Cox* (U.S. Patent No. 6,540,774).

As discussed above, with regard to traversal of the rejection under 35 U.S.C. §102(b), *Wolinsky* does not teach or suggest all of the limitations of claim 1, and cannot therefore, by itself, provide the proper basis for rendering obvious any claims depending from claim 1. See MPEP 2143.03 (To establish *prima facie* obviousness of a claimed

invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)).

Applicants also note that the stents in *Wolinsky* are quite different from the stents in *Cox* with each having different configurations. Thus, without engaging in impermissible hindsight there is no motivation for one of ordinary skill in the art at the time of the invention to modify the stent in *Wolinsky* to interconnect the struts as taught by *Cox* by use of hinge elements having a width narrower than a width of the struts. *See Ruiz*, 234 F.3d 654, 665 (Fed. Cir. 2000) (explaining that the temptation to engage in impermissible hindsight is especially strong with seemingly simple mechanical inventions). *See also Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999) (“[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight.”) *See also In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000) (“Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.”)

Applicants kindly request that the Examiner find in the references themselves (*Wolinsky* or *Cox*) the motivation or suggestion to modify the stent disclosed in *Wolinsky* to interconnect the struts as taught by *Cox* by use of hinge elements having a width narrower than a width of the struts.

With regard to claim 3, as discussed above concerning the Applicant’s traversal of the rejection under 35 U.S.C. §102(b), *Wolinsky* does not teach or suggest all of the limitations of claim 1, and cannot therefore, by itself, provide the proper basis for rendering obvious any claims depending from claim 1. *See* MPEP 2143.03. Moreover, Applicants respectfully disagree with the Examiner’s assertion that *Wolinsky* Fig. 11 teaches of “plurality of generally linear interconnecting elements further comprise generally curvilinear first and second terminal sections at opposing ends of each interconnecting element that join the struts.” *Wolinsky* Fig. 11 does not teach of curvilinear terminal sections as disclosed by Applicants. If the Examiner disagrees with the Application’s understanding of *Wolinsky* Fig. 11, Applicants kindly request that the

Examiner explain in detail how and where in *Wolinsky* Fig. 11 does it show “plurality of generally linear interconnecting elements further comprise generally curvilinear first and second terminal sections at opposing ends of each interconnecting element that join the struts.”

With regard to claim 4, Applicants note that the Examiner did not provide any reason for the §103(a) rejection of claim 4.

With regard to claim 5, Applicants note that as discussed above, Examiner has not convincingly explained how *Wolinsky* Fig. 11 shows the curvilinear terminal sections as disclosed by Applicants.

D. Claim 10 is in condition for allowance.

The Examiner objected to claim 6 as being dependent upon a rejected claim base, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants canceled claim 6 and rewrote original dependent claim 6 in independent form to be new independent claim 10. Claim 10 incorporates all of the limitations of claims 1-5 and is therefore in condition for allowance.

E. Newly added claim 11 is patentable over the prior art.

Claim 11 has been added to more clearly describe the Applicants' invention. Claim 11 introduces a “strain relief sections” feature that was not present in any of the original. Support for the “strain relief sections” aspect of the Applicant's invention can be found in the application as filed from page 9 line 30 to page 10 line 7. None of the cited references, *Wolinsky*, *Burgermeister* or *Cox*, teach employing strain relief sections for accommodating offset angular orientation of interconnecting elements and for providing for folding of interconnecting members during compression of the stent from its larger diameter to its smaller diameter. Accordingly, claim 11 is allowable over the prior art.

***Summary***

The Examiner's rejections of claims 1-5 and 7-9 have been obviated by the above remarks. Accordingly, Applicants submit that the pending claims are patentably distinct from and over the art cited and of record. Favorable reconsideration of the rejection of the pending claims is solicited. Also, original claim 6 has been cancelled and rewritten in independent form as claim 10 to include all of the limitations of claims 1-5 and is therefore in condition for allowance. New claim 11 has been added and is patentable over the prior art. If any question remain that may be resolved in a telephone interview, Applicants ask the Examiner to contact the undersigned.

This Amendment is being concurrently filed with an Amendment Transmittal Letter including a fee calculation sheet, any applicable Request for Extension, and fee calculations. The Director is authorized to deduct any additional expenses from Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Should the Examiner find that there are any outstanding matters which are susceptible of resolution by telephone interview, the Examiner is invited to telephone the undersigned to discuss the same.

Respectfully submitted

A handwritten signature in black ink, appearing to be 'P. J. Lee' with a stylized flourish at the end.

Paul J. Lee  
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